

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S and	)	
ANTON ANTON MAYR,	)	
	)	
Plaintiff,	)	
v.	)	C.A. No. 05-614 (SLR)
	)	
ACAMBIS INC. and	)	<b>REDACTED</b>
ACAMBIS PLC,	)	<b>PUBLIC VERSION</b>
	)	
Defendants.	)	
	)	
	)	

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**APPENDIX TO  
OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS,  
OR IN THE ALTERNATIVE FOR SUMMARY JUDGMENT, ON ALL CLAIMS**

MORRIS, NICHOLS, ARSH & TUNNELL LLP  
Mary B. Graham (#2256)  
Rodger D. Smith II (#3778)  
James W. Parrett, Jr. (#4292)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
302.658.9200

OF COUNSEL: *Attorneys for Defendants  
Acambis Inc. and Acambis plc*

William D. Coston  
Linsday B. Meyer  
Martin L. Saad  
Tamany J. Vinson Bentz  
VENABLE, LLP  
575 7<sup>th</sup> Street, NW  
Washington, DC 20004-1601  
202.344.4000

Dated: December 7, 2006  
Redacted Version Filed: December 18, 2006  
549286

**TABLE OF EXHIBITS**

<b>Exhibit</b>	<b>Description</b>
1	Letter from Pascale to Graham, August 23, 2006
2	Deposition Transcript, Anton Mayr (September 21, 2006)
3	ITC Order No. 27, Initial Determination Granting in Part Respondent's Motion for Summary Judgment (April 17, 2006)
4	ITC Joint Statement of Undisputed Facts ("JSUF") (March 20, 2006)
5	Deposition Transcript, Anton Mayr (December 14, 2005)
6	"MVA Vaccination Against Smallpox," Stickl, Anton Mayr et al. (1974)
7	Deposition Transcript, Joseph Straus (November 30, 2006)
8	Straus Second Supplemental Expert Report (December 6, 2006)
9	Anton Mayr et al., Infection 3:1 (1975)
10	ITC Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bonding (September 6, 2006)
11	ITC Transcript, Direct Testimony Robert Drillien (April 17, 2006)
12	ITC Hearing Transcript, Robert Drillien (May 8, 2006)
13	Letter from Anton Mayr to Alice Bennett (June 30, 1995)
14	Deposition Transcript Peter Wulff deposition (February 9, 2006)
15	"History of MVA 1974 Stock" from NIH (August 22, 2002)
16	Notes "History of vaccinia virus strain MVA"

Exhibit	Description
17	Notes re: April 28, 2005 meeting with Anton Mayr
18	Peter Wulff Email (November 10, 2004)
19	Email Correspondence between Peter Wulff and Anton Mayr (November 11, 2004)
20	Deposition Transcript Peter Wulff (September 21, 2006)
21	Truiken Heyden letter to [REDACTED] (December 19, 2003)
22	Minutes from February 3, 2004 meeting with [REDACTED]
23	Peter Wulff email (September 8, 1999)
24	Anton Mayr letter to Bernard Moss (September 1995)
25	Bernard Moss letter to Anton Mayr (August 3, 2001)
26	NIH lab notebook recording receipt of MVA 572
27	Anton Mayr letter to Bernard Moss (September 12, 2001)
28	Bernard Moss letter to Anton Mayr (April 23, 2003)
29	Handwritten notes of Linda Gritz
30	Deposition Transcript Linda Gritz (February 8, 2006)
31	Deposition Transcript Robert Drillien (November 24, 2006)
32	Request For Proposal-1
33	April/May 2002 email correspondence between Peter Wulff and NIH

Exhibit	Description
34	November 2002 Letters from Anton Mayr to NIH
35	Michael R. Mowatt letter to Peter Wulff (July 15, 2002)
36	Bavarian Nordic's Responses and Objections to Acambis' First Requests for Admissions, No. 132.(December 1, 2005)
37	Peter Wulff letter to John R. La Montagne (March 27, 2003)
38	John R. La Montagne letter to Peter Wulff (June 30, 2003)
39	Acambis NIAID Biological Materials Transfer Agreement. (September 27, 2002)
40	Deposition Transcript, Cynthia Lee (February 2, 2006)
41	Therion-NIAID Biological Materials Transfer Agreement (March 7, 2003)
42	Letter from Mowatt to Acambis (January 17, 2003)
43	Assignment Agreement between Bavarian Nordic A/S and Anton Mayr (November 6, 2002)
44	Agreement between Bavarian Nordic and Anton Mayr (May 28, 1996)
45	Agreement between Bavarian Nordic and Anton Mayr (June 1, 2001)
46	Supplemental Agreement between Bavarian Nordic and Anton Mayr (March 24, 2004)
47	Deposition Transcript, Clement Lewin (September 29, 2006)
48	Acambis' Investigational New Drug Application (January 29, 2004)
49	Diagrams of Baxter's production process flow sheet

Exhibit	Description
50	Expert Report of John C. Jarosz (October 12, 2006)
51	Expert Report of Robert Drillien (October 12, 2006)
52	Supplemental Expert Report of Joseph Straus (November 29, 2006)
53	Bavarian Nordic A/S's Confidential Second Supplemental Responses to Acambis' First Set of Interrogatories (Nos. 1-12) to Bavarian Nordic, (September 18, 2006)
54	Acambis Response to RFP-3 §4.2.2, (October 3, 2005)
55	Bavarian Nordic ITC Third Supplemental Response to Interrogatory Nos. 29 and 30 at 7 (January 27, 2006)
56	Bavarian Nordic A/S Objections and Responses to Acambis' First Set of Interrogatories, (February 23, 2006)
57	Krista Lynch letter to counsel for Acambis (October 13, 2006)

**CERTIFICATE OF SERVICE**

I hereby certify that on December 18, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw, Esquire  
YOUNG CONAWAY STARGATT & TAYLOR LLP  
The Brandywine Building, 17<sup>th</sup> Floor  
1000 West Street  
Wilmington, DE 19801

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on December 18, 2006 upon the following individuals in the manner indicated:

**BY E-MAIL AND HAND DELIVERY**

John W. Shaw, Esquire  
YOUNG CONAWAY STARGATT & TAYLOR LLP  
The Brandywine Building, 17<sup>th</sup> Floor  
1000 West Street  
Wilmington, DE 19801

**BY E-MAIL AND FEDERAL EXPRESS**

Edward A. Pennington  
BINGHAM McCUTCHEN LLP  
3000 K Street, Suite 300  
Washington, DC 20007

*/s/ James W. Parrett, Jr.*

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James W. Parrett, Jr. (#4292)

-104-

3. This ID shall become the determination of the Commission 45 days after its date of service unless the Commission within those 45 days shall have ordered review of this ID, or certain issues herein, pursuant to 19 C.F.R. § 210.43(d) or § 210.44.



Robert L. Barton, Jr.

Administrative Law Judge

Issued: September 6, 2006

# EXHIBIT 11

# CONFIDENTIAL EXHIBIT

# EXHIBIT 12

# CONFIDENTIAL EXHIBIT

# EXHIBIT 13

# CONFIDENTIAL EXHIBIT

## EXHIBIT 14

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## EXHIBIT 24

JUL-01-2002 14:11 NIH/NIAID/LUD  
PROF.DR.DR.H.C. MUL. ANTON MAYR  
Institut für Med. Mikrobiologie,  
Infektions- und Seuchenmedizin  
der Tierärztlichen Fakultät  
Veterinärstr. 13  
D-80539 MÜNCHEN

381 480 1147 P.02

München, den 19.09.95

An  
Dr. Bernard Moss  
Laboratory of Viral Diseases  
Building 4, Room 229  
National Institutes of Health  
Bethesda, MD 20892-0455

Dear Mr. Moss,

Thank you for your interest in our MVA-strain.

We are able to send you some samples of our  
- seed virus and  
- vaccine.

1) seed virus: "MVA"

2 vials: 575. FHE-Pass. v. 14.12.83

2 ml (freeze-dried)

2) vaccine: "Vacc.-virus MVA"

3 vials: II/85

1 ml (freeze-dried).

Sincerely yours,

*Dr. Rausch*

Prof. Dr. Dr. h.c. mult. Anton Mayr  
Lehrstuhl für Mikrobiologie  
und Seuchenhygiene  
Veterinärstraße 13  
80539 München

## EXHIBIT 25

EXHIBIT

7



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Laboratory of Viral Diseases, NIAID  
National Institutes of Health  
Building: 4, Room: 229  
4 Center Drive, MSC 0445  
Bethesda, MD 20892-0445  
Phone: 301-496-9869; Fax: 480-1147  
Email: bmoss@nih.gov

August 3, 2001

Prof. Anton Mayr  
Lehrstuhl für Mikrobiologie und Seuchenlehre  
Ludwig-Maximilians-Universität München  
Veterinaerstr. 13  
80539 Muenchen  
GERMANY

Dear Prof. Mayr,

Gerd Sutter told me the good news that you have been able to locate an early sample of MVA in your freezer and have agreed to send it to me. I wish to thank you for your generosity in this regard. As you are aware, MVA has taken on a new life as the premier vaccinia virus vector. I have enclosed a reprint of a recent paper that clearly illustrates the great potential value of MVA.

I understand that Gerd will help with the shipping of the MVA. He has also indicated that he is willing to help with a draft of a letter of authentication of the MVA in order to satisfy the regulatory agencies here.

Again, I thank you for your kindness in this matter.

Sincerely yours,

Bernard Moss M.D., Ph.D.  
Chief, Laboratory of Viral Diseases

cc: Dr. Gerd Sutter

# EXHIBIT 26

# CONFIDENTIAL EXHIBIT

# EXHIBIT 27

CX-262C:1

ACAMBISS CONFIDENTIAL BUSINESS INFORMATION, SUBJECT TO PROTECTIVE ORDER

EXHIBIT

14

01/07/2005 12:07 FAX 8053724747  
7904-JUL 7 2005 11:45AM CLAW DEPT-ARRESTKUNF 345 474 0330DRAFT LEGAL DEPT  
JUL 5 2005 11:45AM CLAW DEPT-ARRESTKUNF 345 474 0330

*Prof. Dr. Dr. h. c. mult. Anton Mayr*  
 Lehrstuhl für Mikrobiologie und Immunologie  
 Ludwig-Maximilians-Universität München

80539 München  
 Veterinärstraße 13  
 Tel. 0892180-2532

Bernard Moss M.D., Ph.D.  
 Chief, Laboratory of Viral Diseases  
 NIAID, National Institutes of Health  
 Building 4, Room 229  
 Bethesda, MD, 20892-0445  
 USA

12. September 2001

Dear Professor Moss,

In response to your request for an early sample of vaccinia Virus MVA I was happy to provide you with the material MVA 572. FHE - 22.02.1974.

This virus material represents lyophilized tissue culture material from the 572nd passage of MVA on primary chicken embryo fibroblasts harvested February 22, 1974 and originates from the vaccinia virus MVA developed and passaged at the Institut für Mikrobiologie und Infektionskrankheiten der Stadt, Ludwig-Maximilians-Universität München (see Mayr et al. 1973, *Passage history, pico partite and applicability of the attenuated vaccinia virus strain MVA, Infection 3:6-14*).

Propagation in chicken embryo fibroblasts through two plaque purification passages (MVA 569.FHE - 12.02.74 and MVA 570. FHE - 15.02.74) and an amplifying passage (MVA 571. FHE - 19.02.74) resulted in the virus stock MVA 572. FHE - 22.02.1974 which was titrated (original titer  $10^{12.5}$  TCID<sub>50/ml</sub>) and lyophilized as standard MVA seedling material. This virus material has been stored at the institute under my control since that time.

With best regards,

Sincerely yours,



Prof. Dr. Dr. h. c. mult. Anton Mayr

TOTAL P. 02

AC0006782

## EXHIBIT 28



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES 2003

Public Health Service

Laboratory of Viral Diseases, NIAID  
 National Institutes of Health  
 Building: 4, Room: 229  
 4 Center Drive, MSC 0445  
 Bethesda, MD 20892-0445  
 Phone: 301-496-9869; Fax: 480-1147  
 Email: bmoss@nih.gov

23 April 2003

Prof. Dr. Dr. h.c. mult. Anton Mayr  
 Lehrstuhl für Mikrobiologie und Seuchenlehre  
 Veterinärstrasse 13  
 80539 München  
 GERMANY

Dear Professor Mayr,

At the request of Dr. Michael Mowatt, Director of the Office of Technology Development at the National Institute of Allergy and Infectious Diseases (NIAID), I have not previously responded to your letter to me, dated 6 November 2002, regarding "MVA and uses thereof." Dr. Mowatt's request stemmed from the very positive meeting held on 8 January 2003 meeting in Bethesda, Maryland with Drs. Peter Wulff and Paul Chaplain of Bavarian Nordic A/S. I understand that the 8 January meeting, which included Drs. John La Montagne, Carole Heilman and Pamela McInnes as well as Ms. Cindy Fuchs and Dr. Mowatt of the NIAID, yielded fruitful discussion of the respective positions of the NIAID and Bavarian Nordic in regard to NIAID's use and distribution the MVA 572.FHE - 22.02.1974 that you provided to me in late summer 2001. Specifically, I understand that Drs. Wulff and Chaplain were to relay to you the amicable conclusions reached during the meeting. In this context I was both surprised and disturbed by Dr. Wulff's letter, dated 27 March 2003, to Dr. John La Montagne of the NIAID (enclosed). For this reason I feel it necessary at this time to address the inaccuracies reflected in your 6 November 2002 letter to me.

Dr. Gerd Sutter brought the F6 isolate of MVA to the National Institutes of Health (NIH) after he received an AIDS scholarship from the Bundesministerium für Forschung und Technologie to work in my laboratory. In 1992, Dr. Sutter and I reported that MVA expressed both vaccinia viral and recombinant proteins at a high level in non-permissive human cells and suggested that MVA would make a safe and efficient vector for vaccines [Sutter and Moss, PNAS 89, 10847, 1992]. These claims were substantiated in a series of animal protection experiments over the next several years [for example: Sutter et al. Vaccine, 12, 1032, 1994; Wyatt et al. Vaccine 14, 1451, 1996; Carroll and Moss Virology 238, 198, 1997; Durbin et al. Vaccine 16, 1324, 1998; Wyatt et al. Vaccine 18, 392, 1999; Stuvelaar et al. J. Virol. 74, 4236, 2000; Amara et al. Science 292, 69, 2001; Earl et al. Virology 294, 270, 2002]. Although the F6 strain was perfectly good for "expression vector work" in the laboratory, it did not have a well-documented passage history. I contacted you in 1995 to request MVA from an original vial of either a vaccine lot or a master seed for the purpose of producing recombinant vaccines for clinical use. In response to my request you generously provided MVA 575 and MVA II/85 without any restrictions. Because the U.S. Food and Drug Administration had expressed concern about the theoretical possibility that the causative agent of bovine spongiform encephalopathy (BSE) was a contaminant in MVA preparations made in the 1980's, I

A. Mayr  
 23 Apr 2003

Page 1 of 2

subsequently requested a vial of an earlier lot. In response to my request you generously provided MVA 572 in the summer of 2001, again with no restrictions. I never received MVA from the European tissue culture collection or from Bavarian Nordic, and therefore am not aware of any restrictions or licenses that you may have placed on the distribution of materials provided to these organizations.

In your 6 November 2002 letter to Dr. La Montagne, you expressed concern regarding the safety profile of the MVA that you provided to me. I must assume that your concerns arose after you shipped MVA 572 to me, as you failed to mention any such concerns whatsoever in the letter, dated 12 September 2001, that you provided to me in response to my request for documentation about the MVA 572 you shipped in the summer of 2001. Nevertheless, I assure you that, before testing in clinical trials any derivatives of MVA 572, the NIAID will undertake, at a minimum, all testing necessary to meet safety standards mandated by clinical regulatory authorities.

I am enclosing a package of reprints describing my studies over the years with MVA. You will see that I have referenced your publications numerous times in order that you receive recognition for your seminal work. I believe that we are all striving toward the goal of enhancing the health and security of the peoples of the world.

Sincerely yours,

*Bernard Moss*

Bernard Moss M.D., Ph.D.  
Chief, Laboratory of Viral Diseases  
Division of Intramural Research, NIAID

Enclosures

cc:	P. Wulff, Bavarian Nordic A/S, via facsimile transmittal: +45 33 26 83 80	without enclosures
	J. La Montagne, Deputy Director, NIAID	without enclosures
	M. Mowatt, Office of Technology Development, NIAID	without enclosures
	S. Sherman, Office of the General Counsel, NIH	without enclosures
	M. Rohrbaugh, Office of Technology Transfer, NIH	without enclosures

A. Mayr  
23 Apr 2003

Page 2 of 2

TOTAL P.8

# EXHIBIT 29

# CONFIDENTIAL EXHIBIT

## EXHIBIT 30

# CONFIDENTIAL EXHIBIT